

REMARKS

Applicants respectfully request reconsideration of the present application in view of foregoing amendments and the reasons that follow.

I. Status of the Claims

Claims 43, 48, 103, 104, and 112 are currently amended. Claims 104 and 106 are canceled. No new matter is introduced.

Claims 1-55, 62, 66-92, 103, 105, and 107-115 are pending, of which claims 1-42 and 66-99 are withdrawn.

II. Provisional Obviousness Type Double Patenting Rejection

The Examiner maintains the provisional rejection of claims 43 as allegedly being unpatentable over claims 1, 12, and 20 of co-pending application 11/171,111. (Final Office Action, page 3)

While both applications are pending with rejections on other grounds, Applicants respectfully request that the provisional obviousness type double patenting rejection be held until the present application is found otherwise allowable. Applicants will respond to the rejection on the merits or file a terminal disclaimer should the rejection be maintained.

III. Rejections under 35 U.S.C. §112, first paragraph

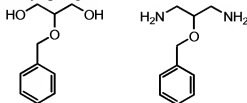
The Examiner rejects claims 103-115 as allegedly failing to comply with the written description requirement. (Final Office Action, page 3)

The Examiner alleges that the recitation of glycerine and 2-hydroxyl-1,3-propylene diamine in claim 103 and the recitation of β -hydroxylmethylbutyrolactone in claim 104 introduce new matter to the application. The Examiner further alleges that the recitation of polymers having components derived from substituted β -butyrolactone, glycerine or 2-hydroxyl-1,3-propylene diamine adds new matter to the application.

Applicants traverse. Those claims are supported by the originally filed application. For instance, the specification at page 15 describes suitable compounds, including glycerine and 2-hydroxyl-1,3-propylene diamine, for attaching phospholipid moieties. The specification states:

“In another embodiment, any suitable compound having three hydroxyl groups can be protected with a protective group such as a benzyl group. The

remaining two free hydroxyl groups can react with an amino acid and be subsequently incorporated into a poly(ester amide) backbone (Scheme 4). Alternatively, a molecule with two amine groups and one hydroxyl group can be used to incorporate a protected hydroxyl group into the poly(ester amide) backbone (Scheme 4). The protective group can then be removed as described above to generate free hydroxyl groups.



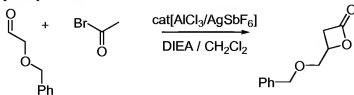
Scheme 4

The phospholipid moieties can be readily introduced into the polymer via the reactive functional groups by simple coupling of the phospholipids moieties with the functional group, with or without a linkage. Representative linkages can be hydroxyl, amino, carboxyl, thiol, or other groups with or without a spacer such as poly(ethylene glycol), etc. Alternatively the phospholipid moieties can be synthesized *in situ* via standard organic reactions (see embodiment below)."

The specification describes the hydroxyl group in glycerine and 2-hydroxyl-1,3-propylene diamine being protected and deprotected in the process of forming a desired polymer.

The specification at page 14 describes suitable monomers for forming the biocompatible polymer, including substituted β -butyrolactone such as β -hydroxylmethylbutyrolactone. The specification states:

"Scheme 2 illustrates another embodiment of the method described herein. A protected hydroxyl aldehyde such as benzyloxyacetaldehyde can undergo cyclization with a halo acyl compound such as acetyl bromide in the presence of a catalyst such as $\text{AlCl}_3/\text{AgSbF}_6$ (in the presence of a base such as (DIEA) diisopropylethylamine to form a butyrolactone such as β -benzoxymethylbutyrolactone.



Scheme 2

Monomers bearing a protected reactive functionality can undergo polymerization alone or copolymerization with other comonomers to form polymers or copolymers bearing protected functionalities. For example, the

substituted ϵ -caprolactone and β -butyrolactone can be copolymerized with glycolide, lactide, or an oxirane such as butyrolactone, valerolactone, or caprolactone to form a polymer or copolymer with different compositions. In one embodiment, a benzyl protected caprolactone can polymerize in the presence of a catalyst such as dioctylstannane ($\text{Sn}(\text{Oct})_2$) to yield a polycaprolactone with benzyl protected hydroxyl groups. The benzyl groups can be cleaved off under acidic conditions to generate free hydroxyl groups (Scheme 3)."

Schemes 2 shows substituted β -butyrolactone such as β -hydroxylmethylbutyrolactone.

In response to the Advisory Action, claim 103 is further amended and claim 104 is canceled.

One skilled in the art would understand that the embodiments were contemplated at the time the present application was filed and therefore the claims do not introduce new matter.

Applicants respectfully request the reconsideration and withdrawal of the rejection.

IV. Rejection under 35 U.S.C. §112, second paragraph

The Examiner rejects claim 112 as allegedly being indefinite. (Final Office Action, page 6)

Claim 112 is currently amended to remove the phrase at issue. The amendment renders the rejection moot.

V. Rejection under 35 U.S.C. §103(a)

A. Hilborn, Koulik, Marchant, Wright, Uhrich, and Falatico

The Examiner rejects claims 43-55 as allegedly being unpatentable over Hilborn (WO 2004/021976) in view of Koulik (EP 0947205), Marchant (US 5,455,040), and Wright (US 6,273,913). (Final Office Action, page 8)

The Examiner rejects claims 43, 45, and 62 as allegedly being unpatentable over Hilborn in view of Koulik, Marchant and Wright, and further in view of Uhrich (US 2004/0096476) and Falatico (US 2001/0029351). (Final Office Action, page 9)

Applicants traverse. The cited art cannot render the claims obvious.

Amended claim 43 recites “the non-fouling moiety is selected from the group consisting of hydroxyethylmethacrylate (HEMA), poly(n-propylmethacrylamide), sulfonated polystyrene, hyaluronic acid, poly(vinyl alcohol), sulfonated dextran, and combinations thereof”.

Neither Hilborn nor Koulik teaches including a non-fouling moiety as recited. The Examiner states that Marchant teaches a polymeric coating having heparin as anti-thrombogenic agent attached to a polymer via PEG; and that Wright teaches incorporating rapamycin in a polymer coating. However the teachings of Marchant and Wright as cited by the Examiner do not suggest any of the non-fouling moieties recited in the amended claim 43.

Therefore the combination of Hilborn, Koulik, Marchant, and Wright cannot arrive at the claimed invention and therefore cannot render claim 43 and its dependent claims obvious.

The Examiner states that Uhrich teaches a polyanhydride ester polymer that degrades into the anti-inflammatory salicylic acid; and that Falatico teaches stents coated with a combination of anti-inflammatory agents with rapamycin and heparin in the coating. However the teachings of Uhrich and Falatico as cited by the Examiner cannot make the deficiency of Hilborn, Koulik, Marchant, and Wright.

Therefore the combination of the cited reference cannot arrive at the claimed invention, and therefore cannot render claims 43, 45, and 62 obvious.

Applicants respectfully request the reconsideration and withdrawal of the rejections.

B. Toner, Durrani, and Gautier, Marchant, Uhrich, and Falatico

The Examiner rejects claims 43-45, 47, 48, and 103-114 as allegedly being unpatentable over Toner (US 2004/0180039) in view of Durrani (Biomaterials 1986 7:121-125) and Gautier (Journal of Biomaterial Science Polymer Edition 2003, 14:63-85). (Final Office Action, page 12)

The Examiner rejects claims 43, 45, 46, 49-55, 103, and 113-115 as allegedly being unpatentable over Toner in view of Durrani and Gautier as applied to claims 43-45, 47, 48, and 103-112, and further in view of Marchant. (Final Office Action, page 14)

The Examiner rejects claims 43, 45, and 62 as allegedly being unpatentable over Toner in view of Durrani, Gautier, Uhrich, Falatico, and Marchant. (Final Office Action, page 15)

Applicants traverse. Claims 104 and 106 are canceled. The rejection of which is moot. The cited art cannot render the remaining claims obvious.

Claims 43 and 103 are currently amended. The amended claims do not encompass the polymer species taught by the references as stated by the Examiner. Therefore the combination of the references cannot arrive at the claimed invention.

At least for the reason set forth above, the cited art cannot render independent claims 43 and 103 and their respective dependent claims obvious. Applicants respectfully request the reconsideration and withdrawal of the rejections.

CONCLUSION

In view of the foregoing amendments and remarks, this application is believed to be in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any fees which may be required regarding this application, or credit any overpayment, to Deposit Account No. **07-1850**. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petitions for such extension and authorize payment of any such extensions fees to Deposit Account No. **07-1850**.

Respectfully submitted,

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